



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,028	12/03/2003	Francine Gervais	NBI-139CP	8334
959	7590	08/10/2006	EXAMINER	
LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109			SAMALA, JAGADISHWAR RAO	
			ART UNIT	PAPER NUMBER
			1618	
DATE MAILED: 08/10/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/728,028

Applicant(s)

FRANCINE GERVAIS

Examiner

Jagadishwar R. Samala

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-102 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restrictions to one of the following inventions is required under 35 U.S.C. 121 :

- I. Claims 1-39, 43-47, 49,50 and 102, an amyloid-targeting imaging agents capable of binding specifically to amyloid fibrils and fibril containing structures (e.g. lesions or plaques) drawn to 424, subclass 1.11.
- II. Claims 40-42, 48, 51-101, methods of diagnosis that are useful for imaging amyloid fibrils in vivo drawn to class 424,subclass 9.3.

Restriction to one of the following inventions is required under 35 U.S.C. 121

1. Inventions imaging agents and method of diagnosis are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, all the amyloids are extracellular protein deposits and have common morphologic properties. These deposits can be detected with specific dyes such as Congo Red which have a characteristic red-green birefringent appearance in polarized light and further share common ultra structural features and common x-ray diffractions and infrared spectrum.

Art Unit: 1618

This application contains claims directed to the following patentably distinct species: 1) specific imaging agent and 2) diagnosis of specific amyloidotic diseases (depending on the elected group). The species are distinct because the species consists of various distinct chemical moieties, e.g. alkyl, alkenyl, aryl, carbonyl, thiocarbonyl, sulfonates, thiosulfonates, tetrazole, aminoacids, peptides, sulfonic acid derivatives, radionuclide, a cationic carrier molecules, a anionic carrier molecule, SEQ ID 1-28, linker groups, etc. and diagnosis of various amyloidotic diseases therapeutically or by various distinct imaging means e.g. radionuclide, ultrasound, x-ray and magnetic resonance imaging techniques.

A plurality of disclosed patentably distinct imaging agents in Group I and II, numerous active agents, for e.g. in claims 20,21,24-27,30,37-39,42,49,65,68,80-82,85,92-94 and 102.

Applicant is required under 35 U.S.C. 121 to elect single disclosed species for prosecution on the merits to which claims shall be restricted if not generic claim is finally held to be allowable. The single disclosed species must specifically identify a composition for all the components present in the claimed invention.

Applicant is advised that a reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

Art Unit: 1618

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571) 272-9927. The examiner can be normally be reached on M-F 8.30 A.M to 5 P.M.

Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

sjr



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER